REMARKS

Applicants submit the following remarks in response to the Office Action dated January 8, 2009. Entry and reconsideration are respectfully requested.

A. Status of Claims

Claims 14-27 are pending.

Upon entry of this response, Claims 14-27 will be cancelled without prejudice or disclaimer, Claims 28-33 will be added, and Claims 28-33 will be pending. No new matter has been added.

With regard to the restriction requirement, Claim 29 recites sodium salt of 2-amino-pyrimido[4,5-d]-6H-pyridazine-5,8-dione, and Claim 33 recites sexual disorders/sexual dysfunction.

B. Response to Claim Rejections under 35 U.S.C. § 112

Claims 16 and 22 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As stated above, Claims 14-16 and 22 have been cancelled without prejudice or disclaimer.

Applicants respectfully assert that Claim 33 is not indefinite because Claim 33 does not require all of the diseases listed in the claim. Claim 33 recites selecting a disease from the group of diseases; Claim 33 does not require selecting each and every disease in the group.

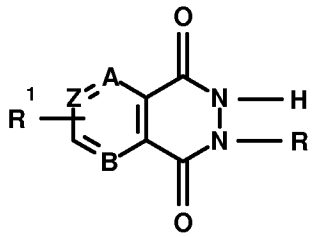
Thus, it is irrelevant whether the diseases overlap because Claim 33 only requires a single disease to be selected.

C. Response to Claim Rejections under 35 U.S.C. § 103

Claims 14-16 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yurugi et al., Chem. Pharm. Bull., vol. 20, pages 1513-1521 (1972) ("Yurugi"), WO 02/09681 to Zhilov ("Zhilov"), and Goldenberg, Clinical Therapeutics, vol. 20, pages 1033-1048 (1998) ("Goldenberg"), in combination. In short, the Office Action asserts that the combination of Yurugi, Zhilov, and Goldenberg discloses each and every feature of the claims.

As stated above, Claims 14-16 and 22 have been cancelled without prejudice or disclaimer.

Applicants assert that none of the cited references, alone or combined, discloses each and every feature of Claims 28-33. Claims 28-33 are drawn to a method of treating diseases caused by disorders of the nitrergic system and/or the dopaminergic system of an organism comprising administering an active ingredient having normalizing effect with respect to nitrergic and dopaminergic systems. The active ingredient is a cyclic bioisostere of derivatives of a purine system having the general formula:



The Office Action states that tetraazanaphthalene derivatives are used as vasodilators (Yurugi), vasodilators are used to treat sexual disorders (Goldenberg), and salts of amino-derivatives are used to prevent and treat various diseases associated with immunopathologic changes (Zhilov). However, none of the cited references, alone or combined, discloses treating diseases caused by disorders of the nitrergic system and/or the dopaminergic system by administering an active ingredient having normalizing effect with respect to nitrergic and dopaminergic systems, the active ingredient being a cyclic bioisostere of derivatives of a purine system, as required by Claims 28-33.

Yurugi discloses 2-phenyl-3,5,7-triaminopteridine (triamterene) as a diuretic agent and 2,7-Bis(2-hydroxyethyl)amino-4,8-dipiperidinopyrimido-[5,4-d]pyrimidine (dipyridamol) as a cardio-vasodilator, but these compounds are very different from the claimed active ingredient, which is not biologically active as a vasodilator. Yurugi also discloses 2-substituted-5,6,7,8-tetrahydropyrimido[4,5-d]pyridazine-5,8- dione, but this compound is also different from the active ingredient required by Claims 28-33. Further, Yurugi does not indicate that a pyridazine-dione would or could function as a diuretic agent or a cardio-vasodilator because Yurugi only specifies two compounds that are capable of these functions. Yurugi also does not disclose that such a compound would or could treat diseases caused by disorders of nitrergic system and/or dopaminergic system. As such, Yurugi does not teach or suggest the claimed active ingredient, and does not teach or suggest treating diseases caused by disorders of nitrergic system and/or dopaminergic system.

The Office Action acknowledges that Yurugi does not discuss pharmacologically acceptable salts or the treatment of sexual disorders or dysfunction.

To remedy this deficiency, the Office Action states that Zhilov discloses preventing and treating various diseases associated with immunopathologic changes, such as toxicoinfectious, oncologic, allergic, or other diseases, using salts of amino-derivatives. However, the structures and treatments disclosed in Zhilov are not the same as, or even similar to, the structure and treatment disclosed in Claim 28-33. Thus, the salts in Zhilov do not rectify the deficiencies of Yurugi. Further, Zhilov discloses diseases of the immune system, but these types of diseases are different from the nitrergic/dopaminergic disorders required by Claims 28-33. Zhilov's compounds do not have the same utility as the claimed compounds because neither Zhilov nor the other cited references discloses administering an active ingredient having normalizing effect with respect to nitrergic and dopaminergic systems. For at least these reasons, Zhilov does not cure the deficiencies of the other references, and there would have been no motivation to combine with Zhilov.

The Office Action further states that vasodilators are important in treating male erectile dysfunction, citing Goldenberg. As stated above, Yurugi only describes a single compound as being a vasodilator, that compound being very different from the active ingredient required by Claims 28-33, and the active ingredient in Claims 28-33 is not biologically active as a vasodilator. Thus, Goldenberg treats sexual disorders in a manner different than the manner disclosed in Claims 28-33. Goldenberg does not disclose normalizing the nitrergic and dopaminergic systems, and does not rectify the deficiencies of the other cited references.

For at least these reasons, Claims 28-33 are distinguishable over the cited references because these references, alone or combined, do not teach each and every feature of the claims. The cited references do not disclose the active ingredient of Claims 28-33, especially

the elected sodium salt of 2-amino-pyrimido[4,5-d]-6H-pyridazine-5,8-dione, and do not disclose a similar method of using the active ingredient to treat diseases caused by disorders of the nitrergic system and/or the dopaminergic system.

CONCLUSION

For at least the reasons stated above, Applicants respectfully request reconsideration, withdrawal of the rejection of claims, and allowance of this application.